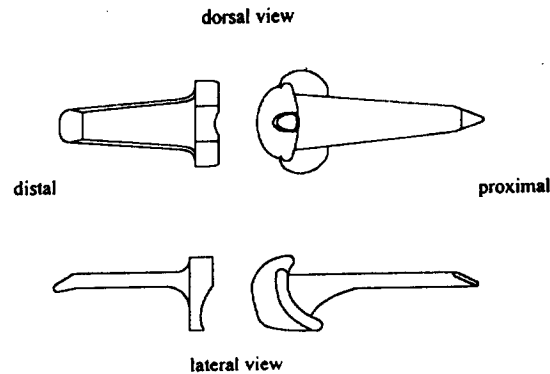


Patient Labeling Brochure



Photograph or drawing of the implant

What is the purpose of the (MCP) joint prosthesis?

HUMANITARIAN DEVICE. The Avanta Metacarpophalangeal (MCP) Finger Prosthesis is authorized by Federal law for use in arthroplasty (surgery) of the MCP joint when either the:

- patient needs the surgery again because a previous joint surgery failed.
- patient expects to use his/her hand under heavy loading (doing heavy lifting) and other types of devices are not useful for this purpose.

The effectiveness of this device for this use has not been demonstrated.

When should the device not be used?-- Contraindications

- When your bone, musculature, tendons, or adjacent soft tissue is damaged by disease, infections or by prior implantation.
- Infection
- When you do not have adequate skeletal support for the implant.
- When you are young and your bones are still growing.

What is my doctor thinking about using for my implant?

- Avanta Orthopaedics has developed an implant for the Metacarpophalangeal (MCP) finger joint. The (MCP) joint is the joint that is also referred to as your knuckle.

- This implant is available for sale in the United States as a humanitarian use device. A humanitarian use device is one, which is used for conditions or diseases which typically affect fewer than 4000 people in the United States per year, and when there is no comparable device marketed to treat/diagnose those conditions or diseases.
- Your physician has determined that you may benefit from implantation of this finger joint implant.
- **You should be aware that the effectiveness of this device for this use has not been demonstrated.**

What will occur during the surgery?

- This surgery involves the use of a finger joint replacement device for treatment of patients with certain kinds of arthritis (osteo-arthritis or post traumatic arthritis) and who expect to place their hands in heavy loading situations, or patients needing revision of a failed implant placed in the MCP joint.
- A joint replacement surgery is an operation where the arthritic joint is removed and a metal and plastic joint is inserted to replace the natural joint. The surgery is expected to last about 2 hours.
- The procedure is done in the operating room and requires general anesthesia or an axillary block. (General anesthesia effects the entire body and is accompanied by a loss of consciousness. An axillary block results in anesthesia of the hand and forearm only. A tourniquet is applied to the arm to prevent bleeding during the surgery.)
- In joint replacement surgery, your hand is opened at the finger joint, and the bones are trimmed. The metal and plastic joint replacement parts are fixed to the bones using bone cement.

Will there be special care after the surgery?

- Antibiotics are usually given during and after the operation to prevent infection, as is normal in these cases, with current surgical treatment.
- Your doctor may give you medicine for pain after surgery.
- After the operation, your hand will be in a bandage. This will be removed two to five days following the operation. You may need to wear a splint or a cast for up to 4 weeks.
- When the bandage or splint is removed, you will start physical therapy.
- Your doctor and therapist will tell you how to take care of your hand. It is very important to follow their instructions and attend all of your appointments.

Are there Warnings I should be aware of?

- It is unlikely that your finger joint will be restored to the condition it was before your injury, arthritis or previous surgery. You should discuss your expectations of having surgery with your doctor before having surgery, as this procedure may not meet your expectations.

- You should be aware that strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. There is an increased potential for device failure when excessive demands are made upon it.

Does this surgery have risks that I should be aware of?

Note: It is important that you discuss all of these risks with your doctor.

General Surgery Related Risks – These are problems you may have because you are having surgery.

- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks – These are problems you may have because you are having this implant placed in your hand.

- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement protrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s)

known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

What Benefits may I hope to receive?

- improved range of motion
- relief of pain
- improved grip and pinch strength.

Are there other treatments that I could receive for my condition?

You should thoroughly discuss the options for treating your finger joint with your doctor before selecting surgery as an alternative. Arthritis of the Metacarpophalangeal Joint can be treated non surgically or with surgery. The non surgical options include the use of splints, joint injections and medications (including the use of aspirin type drugs).

Current surgical treatments include fusion of the bones together, surgery on the joint with tendon or joint replacement with silicone implants. Joint replacement, with silicone implants has been available for a number of years and has the advantages of relieving pain and allowing motion at the joint. Some of the risks of silicone implants include the possibility for breakage, deformation, and side to side instability. If you are very active and use your hands heavily, you may not be good candidates for silicone implants.

What can I expect after surgery?

You should be aware, all implants will wear over time with use. It is important that you ask you surgeon what range of motion you may hope to have after the surgery and what strength you may hope to regain These factors will vary from one patient to another Therefore some degree of wear particle formation is inevitable with all implants including those made of silicone. The patient's biological response to these particles is variable. There are also reports in the medical literature suggesting a possible link between silicone implants and immunological abnormalities and autoimmune rheumatic disorders.

Glossary

Amputation – The removal of your entire finger or limb.

Antibiotics – Medication used to treat infection caused by bacteria and other microorganisms.

Axillary Block – A type of anesthetic, which numbs only the hand and forearm. You stay awake during the surgery with this type of anesthesia.

Immunological abnormalities – A condition which results in inadequate or ineffective functioning of your bodies immune system.

Instability – The joint doesn't provide enough support to resist your activities and may slide off to the side.

Metacarpophalangeal (MCP) finger joint – Commonly referred to as your knuckle.

Revision Surgery – A joint or implant may need more than one surgery if the first surgery doesn't work as well as expected.

Therapist – A person who will help you care for your hand after surgery to give you the best result possible. This person works with your doctor to treat your hand.

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